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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/673,680

09/26/2003

Robert L. Doubler

2131.023

2033

43541

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10/20/2006

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EXAMINER

SWIGER III, JAMES L

ART UNIT

PAPER NUMBER

3733

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/673,680 | Applicant(s) DOUBLER ET AL. | |
| | Examiner James L. Swiger | Art Unit 3733 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 15-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 8/2/2006 have been fully considered but they are not persuasive.

With regards to the arguments against the Mullane reference, it is held that the reference still meets the limitations of the amended claims. The amount of torque applied to the fixation system is relative to the user assembling the device and what is required in the surgery, so a greater or lesser torque would not necessarily affect the structure of the Mullane reference meeting the claim limitations. In reference to a "non-rotational force acting on the linear fastener, even though a device may be used to add a rotational force, per-se, as it acts on what is considered the linear fastener, it is a downward, at least *linear* force to secure the linear fastener. In other words, a rotational force, per-se, and as mentioned above is relative to what the user may require or provide, may rotate, but at least indirectly applies a linear force as required to the linear fastener. Further the retention collet (24) and the linear fastener (46') are still considered to meet with regards to structure, but in addressing what is now defined as "first," this is recited functionally in the claims.

The following rejections still apply:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

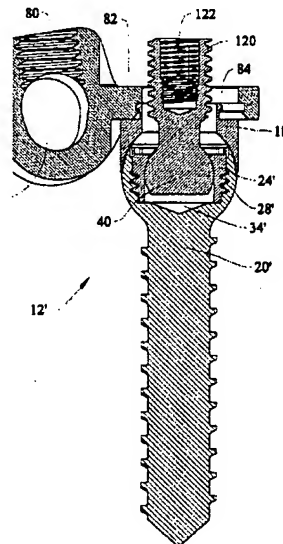
A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 9 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Mullane (US 6,050,997). Mullane discloses a device for use in spinal fixation comprising a polyaxial bone screw (Fig. 2) that is capable of engagement into bone with an effective amount of torque (via threads, note 26 in Fig. 2), and that has a second end that is adapted for swivelable attachment to a linking member (Fig. 3, 32). Mullane further discloses a connecting member (82), and a portion that is capable of function as linear fastener. See Drawing of Fig. 14 below. The linear fastener also would fixedly engage about the linking member end to produce a clamping force.

FIG. 14



In addition to the bone screw of Fig. 2 having a substantially spherical second end (opposite the threaded portion), Mullane also discloses a support collar (18), with a substantially spherical first surface and a generally flat second surface both of which aid

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in providing a clamping force for locking the linking element. See Fig. 14 above. Mullane further discloses a collet member (24') with a tapered inner compression surface (see Fig. 14 above), and also a linking member tensioning means that has an internal bore with threads (122) that is capable being gripped by a threaded attachment to provide the necessary tensile force with respect to the collet.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-4, 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mullane '997 in view of Bradley, Jr. (US 4,684,284). Mullane discloses the claimed invention except for a compression ring member with a base and front end and an inner tapered compression surface. Bradley, Jr. discloses a compression ring (23) with a base end (24) and a front end (considered opposite side of 24); and a tapered compression surface (see curved portion proximate to 23). The curved surface and the compression ring allows locking engagement via a load compression. (Col. 2, lines 45-50). This arrangement is also capable of appropriate clamping/gripping due to the arrangement of the ring and the wedge surface in overlapping engagement with the collet member. It would have been obvious to one having ordinary skill in the art at the

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time the invention was made to construct the device of Mullane having at least a compression ring member in view of Bradley, Jr. to better engage with the collet in either first or second positions to secure the fixation assembly.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mullane '997 in view of Harms et al. (US 4,946,458). Mullane discloses the claimed invention except for a groove extending around the circumference of the first end of the linking element. Harms et al. discloses a portion that is capable of being a groove around a linking element (Fig. 1, 17). Though disclosed as a "bore" it is considered as a groove around the appropriate end of a linking element, and is further capable of receiving a locking pin or any means for that matter as a means for gripping and providing a tensile load on the linking member (Col. 2, lines 50-54). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Mullane having at least a groove around the linking member in view of Harms et al. to better place a tensile load on the linking member.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mullane '997 in view of Hegde et al. (US Pub 2004/0162558 A1). Mullane discloses the claimed invention except for a portion of the tensioning means that includes a frangible stem. Hegde et al. disclose a portion of a threaded head extension (180) that is frangible, or that which may be broken off as needed, or when a preferred tension is reached [par 0043]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Mullane having at least a portion of the tension means has a frangible stem that is capable of being broken at a predetermined

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tension in view of Hegde et al. to better fit the device to its appropriate use in attachment to the spine.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLS

 10/12/04


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER